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CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			KRONENTHAL, CRAIG W	
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			2623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/065,854	UPPALURI ET AL.	
	Examiner	Art Unit	
	Craig W. Kronenthal	2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/03, 11/26/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Regarding Claims 1-57: This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that dual or multiple energy images would include a high energy image, a low energy image, a bone image, and a soft tissue image as is well known in the art of diagnostic medical image processing.

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4. Claims 2-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from one of X-ray radiographic imaging, X-ray computed tomography, or digital x-ray tomosynthesis methods as is commonly performed in the art.

5. Claim 5 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/063,819.

6. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/063,819.

7. Claim 7 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/063,819.

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8. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/063,819.

9. Claim 9 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/063,819.

10. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/063,819.

11. Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 10/063,819.

12. Claim 12 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/063,819.

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13. Claim 13 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/063,819.

14. Claim 14 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/063,819.

15. Claim 15 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 10/063,819.

16. Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 10/063,819.

17. Claim 17 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/063,819.

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18. Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/063,819.

19. Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/063,819.

20. Claim 20 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/063,819.

21. Claim 21 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/063,819.

22. Claim 22 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/063,819.

23. Claim 23 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending

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Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art that the bone image and soft tissue image could be substituted with first and second decomposed images:

24. Claims 24-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from one of X-ray radiographic imaging, X-ray computed tomography, or digital x-ray tomosynthesis systems as is commonly performed in the art. Specifically with regards to claim 26, it would have been obvious that a plurality of high and low images would have been acquired as is common when a computed tomography system is utilized.

25. Claim 28 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art that the bone image and soft tissue image could be substituted with first and second decomposed images.

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26. Claims 29-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from one of X-ray radiographic imaging, X-ray computed tomography, or digital x-ray tomosynthesis systems as is commonly performed in the art. Specifically with regards to claim 31, it would have been obvious that a plurality of high and low images would have been acquired as is common when a computed tomography system is utilized.

27. Claim 33 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that dual or multiple energy images would include a first decomposed image, a second decomposed image, a high energy image, and a low energy image as is well known in the art of diagnostic medical image processing.

28. Claim 34 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 22 of copending Application No. 10/063,819.

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29. Claim 35 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of copending Application No. 10/063,819.

30. Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending Application No. 10/063,819.

31. Claim 37 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 10/063,819.

32. Claim 38 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of copending Application No. 10/063,819.

33. Claim 39 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25 of copending Application No. 10/063,819.

34. Claim 40 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/063,819.

35. Claim 41 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 27 of copending Application No. 10/063,819.

36. Claim 42 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of copending Application No. 10/063,819.

37. Claim 43 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/063,819.

38. Claim 44 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30 of copending Application No. 10/063,819.

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39. Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 33 of copending Application No. 10/063,819.

40. Claim 46 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of copending Application No. 10/063,819.

41. Claim 47 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 35 contains all the limitations of claim 47.

42. Claim 48 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 10/063,819.

43. Claim 49 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 37 of copending Application No. 10/063,819.

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44. Claim 50 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 38 of copending Application No. 10/063,819.

45. Claim 51 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 39 of copending Application No. 10/063,819.

46. Claims 52 and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from computed tomography as is commonly performed in the art.

47. Claim 53 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from volumetric computed tomography as is commonly performed in the art.

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48. Claim 54 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art that the bone image and soft tissue image could be substituted with first and second decomposed images.

49. Claim 55 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the dual or multiple energy image set would be acquired from x-ray tomosynthesis as is commonly performed in the art.

50. Claim 56 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/063,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art that the bone image and soft tissue image could be substituted with first and second decomposed images.

Claim Rejections - 35 USC § 102

51. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one-year prior to the date of application for patent in the United States.

52. Claims 1, 5-8, 13-15, 17, 18, 23, 34, 35, 42, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al. (PN 6,205,348). (hereinafter Giger)

Regarding Claim 1: Giger discloses a method for computer aided processing of dual or multiple energy images, the method comprising:

- employing a data source, the data source including a dual or multiple energy image set including a high energy image, a low energy image, a bone image, and a soft tissue image [Figure 22 illustrates two methods of obtaining dual energy radiographic images (col. 7 lines 47-51).];
- defining a region of interest within an image from the dual or multiple energy image set [Figure 23B. A region of interest (ROI) is selected for both the high energy and low energy images (col. 8 lines 65-67).];
- extracting a set of feature measures from the region of interest [Figure 23B. A measure related to bone mass is calculated for each image (col. 8 line 67 – col. 9 line 3).]; and,

- reporting the feature measures on the region of interest [Figure 28. The results are superimposed onto the images (col. 10 lines 46-47).].

Regarding Claim 5: Giger discloses the method of claim 1 further comprising employing a feature selection algorithm on the region of interest and classifying the region of interest [Figure 28. The artificial neural network (ANN) uses the features to classify the image as being normal or abnormal (col. 10 lines 42-44).].

Regarding Claim 6: Giger discloses the method of claim 5 further comprising incorporating prior knowledge from training for classifying the region of interest [The artificial neural network was trained using prior knowledge of 43 cases to classify regions of interest (col. 11 lines 35-38).].

Regarding Claim 7: Giger discloses the method of claim 6 wherein incorporating prior knowledge from training includes computing features on known samples of different normal and pathological medical conditions [The artificial neural network learns from the features of known examples (col. 11 lines 42-47).].

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Regarding Claim 8: Giger discloses the method of claim 7 wherein the feature selection algorithm sorts through the features of known samples, selects useful features of known samples, and discards features of known samples which do not provide useful information [The artificial neural network utilizes threshold values to discard features which produce outputs different from the desired results (col. 11 line 65 – col. 12 line 13).].

Regarding Claim 13: Giger discloses the method of claim 5 wherein classifying the region of interest using the optimal set of features comprises classifying one or more medical conditions [The artificial neural network uses the features to classify the bone as being osteoporotic or normal (col. 11 lines 37-38).].

Regarding Claim 14: Giger discloses the method of claim 5 wherein the data source further includes at least one of image acquisition system information and demographic information, symptoms, and history of patient, wherein the image acquisition system information, demographic information, symptoms, and history of patient serve as feature measures in the feature extraction algorithm [Image acquisition information, such as scatter radiation, and patient history, such as patient body size, are examples of feature measures used to calculate the bone mass (col. 8 line 67 – col. 9 line 3).].

Regarding Claim 15: Giger discloses the method of claim 1 further comprising detecting and diagnosing at least one medical condition [Figure 28 shows the detecting and diagnosing of the risk of future bone fracture (col. 10 lines 42-45).].

Regarding Claim 17: Giger discloses the method of claim 1 wherein defining a region of interest comprises utilizing an automated algorithm [Figure 28. The selection of a region of interest is done by a circuit and therefore is an automated process (col. 10 lines 30-31).].

Regarding Claim 18: Giger discloses the method of claim 17 wherein utilizing an automated algorithm includes inputting user specifications [The user specifies the placement of a 64x64 pixel ROI (col. 4 lines 20-28).].

Regarding Claim 23: Giger discloses a system for computer aided processing of dual energy images, the system comprising:

- a detector generating a first image representative of photons at a first energy level passing through a structure and a second image representative of photons at a second energy level passing through the structure [Figure 22. The two detectors absorb photons having different levels of energy (col. 8 lines 47-51) and therefore obtain dual energy radiographic images (col. 7 lines 47-51).];

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- a memory coupled to the detector, the memory storing the first image and the second image [Figure 28. The image acquisition device obtains the images and inputs them to memory (col. 10 lines 24-28).];
- a processing circuit coupled to the memory, the processing circuit processing a dual energy image set including a first decomposed image, a second decomposed image, a high energy image, and a low energy image from the first image and the second image [Figures 22 and 28. The memory is connected, via the image acquisition device, to the processing circuit, which begins with the ROI selection circuit (col. 10, lines 24-31). The processing circuit receives dual energy images including high energy images, low energy images, "bone-cancelled" (soft-tissue) images, and "soft-tissue-cancelled" (bone) images (col. 7 lines 43-51).];
- storing the dual energy image set in the memory as a data source [Inputting the images into memory reads on storing to memory (col. 10 lines 27-28).];
- defining a region of interest within an image from the dual energy image set [See analogous arguments in claim 1.];
- extracting a set of feature measures from the region of interest [See analogous arguments in claim 1.]; and,
- a reporting device coupled to the processing circuit, the reporting device reporting at least one feature [See analogous arguments in claim 1.].

Regarding Claim 34: Giger discloses a method for detecting bone fractures, erosions, calcifications or metastases, the method comprising:

- utilizing a bone image from a dual or multiple energy image set [Figure 28. The radiographic images, which include a bone image or "soft-tissue-cancelled" image, is input via the image acquisition device (col. 10 lines 24-28).];
- selecting a region of interest within the bone image to search for a calcification, fracture or metastatic bone lesion [Figure 28. The region of interest is selected to ultimately determine the risk of future fracture (col. 10 line 46).];
- segmenting bone from a background of the bone image [Figure 28. The weighted sum circuit is used to segment the bone from a background to produce a bone-only image (col. 10 line 36 and col. 9 lines 47-52).]; and,
- identifying a candidate region within the bone as a candidate for a calcification, fracture or metastatic bone lesion [Figure 28. The ANN uses measures of bone mass and bone structure to determine a candidate for fracture (col. 10 lines 42-44).].

Regarding Claim 35: Giger discloses the method of claim 34 further comprising classifying an identified candidate region [See analogous arguments of claim 5.].

Regarding Claim 42: Giger discloses the method of claim 34 wherein identifying a candidate region comprises utilizing an edge detection algorithm [The edges of a vertebral body are detected to locate the ROI (col. 9 lines 59-61).].

Regarding Claim 45: Giger discloses the method of claim 34 further comprising indicating candidate regions on a display (col. 10 lines 48-50).].

53. Claims 47-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishikawa et al. (PN 6,058,322). (hereinafter Nishikawa)

Regarding Claim 47: Nishikawa discloses a method for detecting lung disease, the method comprising:

- utilizing a soft-tissue image from a dual or multiple energy image set [Figures 1 and 6B. Exposure X is a soft tissue image of a breast obtained in the image acquisition step (10) (col. 9 lines 65-67).];

- selecting a region of interest within the soft-tissue image to search for an indication of disease [The region of interest selected is the breast (col. 9 line 67).];
- segmenting the region of interest from a background of the soft-tissue image [Figure 1. The ROI, in this case the breast, is segmented from a background in step 20 (col. 8 lines 35-39).];
- identifying a candidate region within the bone image which correlates to the region of interest in the soft-tissue image [The difference between exposures X and X' yield the bone image (col. 10 lines 4-5). The microcalcification in this bone image is then discovered and its radiation contrast is determined (col. 10 lines 3-4).];
- extracting features from the candidate region in the bone image [Features of a microcalcification, which is the candidate region are measured (col. 17 lines 7-8).]; and,
- classifying the region of interest in the soft-tissue image as a candidate for soft-tissue disease utilizing the features extracted from the bone image [Figure 1. The ANN (50) inputs the features to classify the region of interest, in this case a microcalcification, as either malignant or benign (col. 7 line 63 – col. 8 line 2).].

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Regarding Claim 48: Nishikawa discloses the method of claim 47, wherein identifying a disease in the soft-tissue image comprises identifying a solitary pulmonary nodule or lesion, and wherein the features extracted from the bone-image are indicative of calcification of the nodule, the method further comprising utilizing the bone-image calcification features to classify the region of interest in the soft-tissue image as probably benign [The analogous arguments in claim 47 are applicable to claim 48. Although the steps in claim 47 are with respect to microcalcifications in breast images, these steps are also applicable to identifying lesions in lungs to diagnose lung diseases (col. 4 lines 40-46).].

Regarding Claim 49: Nishikawa discloses the method of claim 47 wherein classifying comprises using a computer aided rule based approach, wherein different rules apply for different medical conditions, and different rules are used for the soft-tissue and bone-images [Figure 1. The ANN (50) is used for multivariate problems because they do not rely upon absolute rules, but instead rely upon rules that can adapt to different conditions (col. 20 lines 3-11).].

Regarding Claim 50: Nishikawa discloses the method of claim 47 further comprising reporting at least one of the features using a marker on a display of each image within the dual or multiple energy image set where the at least one feature is located and displaying a single image which incorporates all markers from each image within the

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dual or multiple energy image set [Figure 30. The markers (740 and 750) from each image are shown together (col. 37 lines 34-47).].

Regarding Claim 51: Nishikawa discloses the method of claim 50 further comprising displaying a single image which incorporates markers uniquely indicative of results from the soft-tissue image that have been further classified based on results from the bone-image [Figure 30. The blue arrows indicate microcalcifications while the red arrows indicate masses (col. 37 lines 41-47).].

Claim Rejections - 35 USC § 103

54. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

55. Claims 2-4, 16, 19, 20, 24-27, 29-32, and 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger.

Regarding Claims 2: Giger discloses the method of claim 1 further comprising acquiring the image set using projection x-ray radiographic imaging [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Projection x-ray radiographic imaging is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.]. The analogous arguments of claim 2 are applicable to claim 24.

Regarding Claims 3: Giger discloses the method of claim 1 further comprising acquiring the image set using x-ray computed tomography [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Computed tomography is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.].

Regarding Claims 4: Giger discloses the method of claim 1 further comprising acquiring the image set using digital x-ray tomosynthesis [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Digital x-ray tomosynthesis is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.].

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Regarding Claim 16: Giger discloses the method of claim 1 wherein defining a region of interest comprises manually selecting a region of interest [It is well known in the art of medical image processing to allow an expert to define the region of interest manually.].

Regarding Claim 19: Giger discloses the method of claim 1 comprising defining regions of interest and incorporating features from all regions of interest on all images [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to define regions of interest in each of the already obtained images and that the features would be incorporated in each image. One of ordinary skill would be motivated to annotate each image to simplify the display for analysis by a user thereby expediting the diagnostic process.].

Regarding Claim 20: Giger discloses the method of claim 1 comprising defining at least one region of interest, employing a feature extraction algorithm, and classifying a candidate region of interest on each image and subsequently combining results of all operations [The analogous arguments of claim 19 are applicable to claim 20.].

Regarding Claims 24 and 29: The analogous arguments of claim 2 are applicable to claims 24 and 29.

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Regarding Claims 25 and 30: The analogous arguments of claim 3 are applicable to claims 25 and 30. It is inherent in a computed tomography system that the detector generates a plurality of first images and a plurality of second images taken of the structure at different angles.

Regarding Claims 26 and 31: The analogous arguments of claim 3 are applicable to claims 26 and 31. It is inherent that a computer tomography system used for acquiring a dual energy system, specifically acquire a plurality of high energy images and a plurality of low energy images.

Regarding Claims 27 and 32: The analogous arguments of claim 4 are applicable to claims 27 and 32. It is inherent in a tomosynthesis system that the detector generates a plurality of first images and a plurality of second images taken of the structure at different angles.

Regarding Claims 52 and 57: The analogous arguments of claim 2, which includes the limitations of claim 1, are applicable to claim 52 and 57.

Regarding Claims 53 and 54: The analogous arguments of claim 3, which includes the limitations of claim 1, are applicable to claim 53 and 54.

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Regarding Claims 55 and 56: The analogous arguments of claim 4, which includes the limitations of claim 1, are applicable to claim 55 and 56.

56. Claims 9-12, 21, 22, 28, 33, 36-41, 43, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Nishikawa et al. (PN 6,058,322) (hereinafter Nishikawa)

Regarding Claim 9: Giger discloses the method of claim 7, but does not disclose determining a feature measure's ability. However, Nishikawa discloses a method wherein the feature selection algorithm comprises determining a feature measure's ability to separate regions into different classification groups [The ANN determines a confidence rating indicating a feature measure's ability to correctly classify candidates as abnormal or normal (col. 31 lines 4-9)]. It would be obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa's ANN to determine confidence ratings because both networks are used to classify candidates. Furthermore, one would be motivated to make this modification to determine classifications based on more accurate features.

Regarding Claim 10: Nishikawa discloses the method of claim 9 wherein the feature selection algorithm further comprises ranking each feature measure in the set of feature

measures based on each feature measure's ability to separate regions into a classification group [The ANN ranks each feature measure based on confidence ratings (col. 31 lines 6-12).].

Regarding Claim 11: Nishikawa discloses the method of claim 10 wherein the feature selection algorithm further comprises reducing quantity of feature measures by eliminating correlated features [The examiner takes official notice that one of ordinary skill in the art would modify the ANN to eliminate correlated feature measures to reduce the number of calculations made by the ANN thereby decreasing processing time.]

Regarding Claim 12: Nishikawa discloses the method of claim 10 wherein the feature selection algorithm further comprises selecting highest ranked feature measure and adding additional feature measures in descending order [The ANN outputs the ranked order of the likelihood of malignancy (col. 32 lines 61-63).].

Regarding Claim 21: Nishikawa discloses the method of claim 1 wherein reporting at least one of the feature measures comprises using a marker on a display of each image within the dual or multiple energy image set where the at least one classified region is located [Figure 30. The arrows (740 and 750) act as markers on the display to indicate classified region of interest (col. 37 lines 41-47).]. It would be obvious to one of ordinary

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skill in the art to modify Giger's display of results to include markers as done by Nishikawa. Furthermore, one would be motivated to make this modification to distinguish regions of interest, especially when there is more than one region of interest in a single image.

Regarding Claim 22: Nishikawa discloses the method of claim 21 further comprising displaying a single image which incorporates all markers from each image within the dual or multiple energy image set [Figure 30. Four views (700, 710, 720, and 730) having markers from each image (740 and 750) are displayed in a single image (200) (col. 37 lines 34-47).].

Regarding Claim 28: Giger discloses a system for computer aided processing of dual energy images, the system comprising:

- detection means for generating a first image representative of photons at a first energy level passing through a structure and a second image representative of photons at a second energy level passing through the structure [See analogous arguments in claim 23.];
- storage means for storing the first image and the second image [See analogous arguments in claim 23.];

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- processing means for: processing a dual energy image set including a bone image, a soft tissue image, a high energy image, and a low energy image from the first image and the second image [See analogous arguments in claim 23.];
- storing the dual energy image set in the memory as a data source [See analogous arguments in claim 23.];
- defining a region of interest within an image from the dual energy image set [See analogous arguments in claim 23.];
- extracting a set of feature measures from the region of interest [See analogous arguments in claim 23.];
- employing a feature selection algorithm on the set of feature measures and identifying an optimal set of features [See analogous arguments in claim 8.];

Giger doesn't disclose the remaining steps of classifying, incorporating, or displaying.

However Nishikawa does disclose a system for processing dual energy images comprising:

- classifying the optimal set of features [See analogous arguments in claim 9.];
and,
- incorporating prior knowledge from training into classifying the optimal set of features [By providing ratings for each feature measure, the ANN is in essence classifying them. These ratings are assigned utilizing prior knowledge of ratings that observers have given to actual cases (col. 30 lines 55-60).]; and,

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- display means for displaying at least one classified region of interest [Figures 31 and 32 display ROIs classified as containing microcalcifications and/or masses (col. 37 lines 48-52).].

It would be obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa ANN because both are used for automated diagnosis using medical images. Furthermore, one would be motivated to modify Giger with Nishikawa to use give more weight to those features that are deemed more important in the diagnosis process.

Regarding Claim 33: Giger discloses a storage medium encoded with a machine readable computer program code, said code including instructions for causing a computer to implement a method for aiding in processing of dual or multiple energy images, the method comprising:

- employing a data source, the data source including a dual or multiple energy image set having a first decomposed image, a second decomposed image, a high energy image, and a low energy image [See analogous arguments in claim 1.];
- defining a region of interest within an image from the dual or multiple energy image set [See analogous arguments in claim 1.];
- extracting a set of feature measures from the region of interest [See analogous arguments in claim 1.]; and,

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- employing a feature extraction algorithm on the feature measures for identifying an optimal set of features [See analogous arguments in claim 8].

It would be obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa's ANN to determine confidence ratings because both networks are used to classify candidates. Furthermore, one would be motivated to make this modification to determine classifications based on more accurate features.

Regarding Claim 36: Giger discloses the method of claim 35 but does not disclose classifying calcifications and metastases. However, Nishikawa discloses a method wherein classifying identified candidate regions comprises using a computer aided rule based approach, wherein different rules apply for calcifications, metastases, erosions, and fractures, and for different types of fractures and different properties of metastases [Figure 1. The ANN (50) inherently uses different rules for each different type of candidate region (col. 20 lines 2-11). Nishikawa discloses that the candidate regions include abnormal regions in digital medical images which encompasses calcifications, metastases, and fractures (col. 1 lines 41-46).]. It would be obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa's ANN to classify other abnormalities in addition to just fractures, which are the only abnormalities explicitly cited by Giger.

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Regarding Claim 37: Giger discloses the method of claim 36 wherein rules are based on size measurements of line edges of the identified candidate regions [Surface area is calculated for each ROI and used to determine the classification (col. 11 lines 5-9).].

Regarding Claim 38: Giger discloses the method of claim 34, including segmenting bone from a background image. Giger does not disclose the segmentation using a region growing algorithm. However, Nishikawa discloses the segmentation wherein segmenting bone comprises utilizing a region growing algorithm [Figure 5. Region growing is used to delineate a microcalcification from an ROI (col. 9 lines 29-34).]. It would be obvious to one of ordinary skill in the art to modify Giger's segmentation with Nishikawa's segmentation to include a region growing algorithm to more accurately identify a bone-only image from the background.

Regarding Claim 39: Nishikawa's the method of claim 38 wherein the region growing algorithm is manually initialized by having a user select a seed point [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to initialize the region growing algorithm with a user selected seed point.].

Regarding Claim 40: Nishikawa discloses the method of claim 38 wherein the region growing algorithm is automatically initialized by utilizing bone attributes to select a seed

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point [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to initialize the region growing algorithm with an automatically selected seed point.].

Regarding Claim 41: Giger discloses the method of claim 34, but does not disclose multi-level intensity thresholding. However, Nishikawa discloses bone segmentation wherein segmenting bone comprises multi-level intensity thresholding [Figure 5. A rough threshold is used first followed by a precise threshold (col. 9 lines 29-34)]. It would be obvious to one of ordinary skill in the art to modify Giger's bone segmentation with Nishikawa's multi-level intensity thresholding to correct a bias formed by residual background variation (col. 9 lines 35-39).]

Regarding Claim 43: Giger discloses the method of claim 42, but does not explicitly disclose using morphological erosion. However, Nishikawa discloses a method of detecting microcalcifications wherein image processing using morphological erosion is used for eliminating noise and false edges [Morphological erosion is used to shrink the object thereby removing noise and false edges (col. 18 lines 42-43)]. It would be obvious to one of ordinary skill in the art to modify Giger's combination of weighted summation and integration methods, used to reduce the number of false edges and noise in the ROI (col. 9 lines 48-61), with morphological erosion as taught by Nishikawa instead of the.

Regarding Claim 44: The method of claim 42 wherein rib edges are eliminated using a connectivity algorithm [The morphological erosion method as explained in claim 29 is used in conjunction with a morphological dilation operator to remove false positives (col. 18 lines 35-55). It is well known that rib edges yield false positives in chest images and therefore would be identified and eliminated by the combination of these processes.]

Regarding Claim 46: Giger discloses the method of claim 45, but does not disclose placing markers on the bone image. However, Nishikawa discloses a method for detecting microcalcifications wherein indicating candidate regions comprises placing a marker on the bone image indicative of a classification of the candidate region [Figure 30. Markers (740 and 750) are placed on the classified regions of interest (col. 37 lines 34-47).]. It would be obvious to one of ordinary skill in the art to modify Giger with Nishikawa's markers to help an observer better understand the results.

Conclusion

57. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Ohkubo et al. (PN 5,910,972) is cited for teaching differencing high and low energy images and extracting features bone images.

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- Oosawa (Pub. No. US 2001/0010732) is cited for teaching the subtraction of dual energy images and comparing them on the same display with features including patient history.
- Doi et al. (Pub. No. US 2002/0172403) is cited for teaching classifying nodules in chest images as benign or malignant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig W. Kronenthal whose telephone number is (571) 272-7422. The examiner can normally be reached on 8:00 am - 5:00 pm / Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (571) 272-7414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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07/07/2005
CWK

JINGGE WU
PRIMARY EXAMINER

